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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/660,466

09/12/2000

Dinesh Mody

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6579

7590

10/12/2006

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EXAMINER

ROANE, AARON F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,466

Applicant(s)

MODY ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 48-50, 52, 54-56, 58-65, 68-75, 87 and 92-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-39, 57, 78, 82-84, 89, 90, 100, 101, 105, 111-113 and 115-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 36-39,48-50,52,54-65,68-75,78,82-84,87,89,90,92-101,105,111-113 and 115-119.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 57, 100, 101, 113, 114 and 116-119 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharkey et al. (USPN 6,126,682).

Regarding claims 57, 100, 101 and 113, Sharkey et al. disclose a system for ablating an interior tissue region of an organ or duct within a body of a patient comprising: an

ablation tool including an elongated device (18) electrically coupled to a transmission line that is electrically coupled to a source of microwave energy (element 20 in figure 3A also see col. 15-17, particularly col. 15, lines 20-30) for delivering sufficient microwave energy to the elongate device to effect ablation of a tissue region within the interior of the organ or duct; and an introducer (the rigid and sharp trocar is then advanced through introducer 12, to pierce annulus fibrosus 122 and enter the disc, see figure 4) that is not connected to the source of microwave energy, said introducer having a proximal end, a sharpened distal end for penetrating through a wall of the organ or duct, and a lumen which is sized and dimensioned for slidable movement of the elongate therein, the elongate device being configured to be deployed into the interior of the organ or duct through the sharpened distal end of the introducer with a deployed shape that is straight and at a skewed angular orientation relative to a longitudinal axis of the introducer, to orient the elongate device in a direction towards and substantially parallel to an interior portion of the penetrated wall for producing a linear lesion at the tissue region of the penetrated wall which is targeted for ablation.

Regarding claim 114, Sharkey et al. disclose the claimed invention, see the portion defined by elements 16, 28 and 29 in figure 3A.

Regarding claim 116, Sharkey et al. disclose the claimed invention, see col. 5-23 and figure 3A and 4.

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Regarding claim 117, Sharkey et al. further disclose a system that integrally provided the probe and the ablation tool, see entire reference.

Regarding claims 118 and 119, Sharkey et al. disclose a handle (12) proximally connected to said probe, and wherein longitudinal sliding of said ablation tool within said probe is facilitated via said handle and a biasing member (e.g. wire, hydraulic and electromagnetic in col. 12) configured to bias said ablation element from said straight configuration to said bent configuration, see col. 11 and 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-39, 78, 82-84, 89, 90, 105, 111, 112 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (USPN 6,126,682) in view of Moss et al. (USPN 5,810,803).

Regarding 36, 37, 78, 111, 112 and 115, Sharkey et al. disclose a system for ablating an interior tissue region of an organ or duct within a body of a patient comprising: an ablation tool including an elongated device (18) electrically coupled to a transmission line that is electrically coupled to a source of microwave energy (element 20 in figure 3A also see col. 15-17, particularly col. 15, lines 20-30) for delivering sufficient microwave energy to the elongate device to effect ablation of a tissue region within the interior of the organ or duct; and an introducer (the rigid and sharp trocar is then advanced through introducer 12, to pierce annulus fibrosus 122 and enter the disc, see figure 4) that is not connected to the source of microwave energy, said introducer having a proximal end, a sharpened distal end for penetrating through a wall of the organ or duct, and a lumen which is sized and dimensioned for slidable movement of the elongate therein, the elongate device being configured to be deployed into the interior of the organ or duct through the sharpened distal end of the introducer with a deployed shape that is straight and at a skewed angular orientation relative to a longitudinal axis of the introducer, to orient the elongate device in a direction towards and substantially parallel to an interior portion of the penetrated wall for producing a linear lesion at the tissue region of the penetrated wall which is targeted for ablation. Although Sharkey et al. disclose an elongate microwave energy radiator and this is certainly an implication of a microwave antenna, they fail to explicitly disclose an elongated antenna device electrically coupled to a coaxial transmission line that is electrically coupled to a source of microwave energy for delivering sufficient microwave energy to the antenna device to effect ablation of a tissue region within the interior of the organ or duct, the coaxial transmission line

including an inner conductor, an outer conductor and a dielectric medium disposed between the inner and outer conductors, the antenna device including an antenna that is coupled to a distal end of the inner conductor of the coaxial transmission line and an enclosure that encapsulates the antenna with a dielectric material. Moss et al. disclose a helical coil microwave antenna device and teach that the microwave antenna (206) is connected to the power source via a coaxial transmission line that is electrically coupled to a source of microwave energy, the coaxial transmission line including an inner conductor (224), an outer conductor and a dielectric medium disposed between the inner and outer conductors (although the outer conductor and the dielectric aren't numbered, the entire reference is littered with references to the coaxial transmission line), the antenna device including an antenna (206) that is coupled to a distal end of the inner conductor of the coaxial transmission line and an enclosure that encapsulates the antenna with a dielectric material in order to provide microwave radiative energy to the tissue. Additionally, Moss et al. also disclose that the microwave antenna is encapsulated by a dielectric material (236 and 238) wherein "the material both fills and surrounds antenna coil (206) is typically a flexible dielectric material. Suitable flexible dielectric materials include, but are not limited to, materials such as silicone," see col. 5, lines 26-49. Sharkey et al. also disclose a shape memory material within the elongate energy delivery portion, see col. 13 and 14. Finally, both Sharkey et al. and Moss et al. disclose steering mechanisms, Sharkey et al. disclose steering capabilities in col. 11-12, Moss et al. disclose a steering mechanism (73) associated with the proximal end of the tool which, upon manipulation, is configured to cause at least a portion of the antenna device to

assume an angular orientation relative to a longitudinal axis of the tool, see col. 12, lines 11-13 and figure 7. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Sharkey as taught by Moss et al., to provide the microwave antenna with a connection to the power supply via a coaxial transmission line that is electrically coupled to a source of microwave energy, the coaxial transmission line including an inner conductor, an outer conductor and a dielectric medium disposed between the inner and outer conductors, the antenna device including an antenna that is coupled to a distal end of the inner conductor of the coaxial transmission line and an enclosure that encapsulates the antenna with a dielectric material in order to provide microwave radiative energy to the tissue.

Regarding claims 38 and 39, Sharkey et al. in view of Moss et al. disclose the claimed invention, see Sharkey et al. figures 3A and 4.

Regarding claims 82-84, Sharkey et al. disclose the claimed invention, see elements 16, 28 and in figure 3A.

Regarding claims 89 and 90, Sharkey et al. disclose a device capable of performing the claimed intended use and/or function, see figures 3A and 4.

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Regarding claim 105, Sharkey et al. disclose the energy delivery portion is configured to produce an electromagnetic field that is concentrated on a side of the energy delivery portion, see element 43 in figure 5A and col. 15, lines 54-67.

Response to Arguments

Regarding the arguments/remarks to the 102 rejections based on Sharkey et al. and the 103 rejections based on Sharkey et al. in view of Moss et al., the examiner simply points out the Sharkey et al. certainly do disclose a ablation device (antenna) and is straight and at a skewed angle with respect to the introducer. The distinction between the presently claimed invention and Sharkey et al. is that the presently claimed invention shows in the drawings that the entire exposed portion of the antenna is straight and at a skewed angle with respect to the introducer and not just a portion thereof as in the Sharkey et al. patent. Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.R. *A.R.*
October 2, 2006

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER